UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
EL PASO DIVISION

MAUREEN WOODHOUSE, Plaintiff vs. SANOFI-AVENTIS U.S., Defendant	C.A. NO. 3:11-cv-113-PRM

DEFENDANT SANOFI AVENTIS U.S. LLC'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

Defendant sanofi-aventis U.S. LLC ("sanofi-aventis") files this Motion to Dismiss Plaintiff's First Amended Complaint pursuant to Federal Rules of Civil Procedure 8(a), 9(b) and 12(b)(6).

INTRODUCTION

Plaintiff Maureen Woodhouse alleges that in December 2008 she sustained injuries from a car accident when she allegedly drove during a sleepwalking episode ("sleep driving") after taking Ambien CR, sanofi-aventis' FDA-approved prescription medication. *See* Plaintiff's First Amended Complaint ("Amended Compl.") at ¶¶ 14 – 17. Plaintiff seeks to recover from sanofi-aventis despite the fact that the FDA-approved label for Ambien CR in effect at the time of the alleged incident included a warning about "sleep driving."

Plaintiff's claims must be dismissed because she has failed to satisfy the pleading requirements of Federal Rules 8 and 12 as articulated by the Supreme Court in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009) and she has failed to plead fraud with particularity, as required by Federal Rule 9(b). Plaintiff's claims must also be dismissed because they are foreclosed by Civil Practices & Remedies Code § 82.007.

FACTUAL BACKGROUND

I. Plaintiff's Allegations

Plaintiff alleges that she was originally prescribed Ambien CR 6.25 mg in January 2007 to treat her insomnia. *See* Amended Compl. at ¶ 12. In December 2008, she was given a sample of the 12.5mg dose by her primary care physician. *See id*. at ¶ 13. Then on December 5, 2008, Plaintiff took one Ambien CR 12.5mg. *Id*. at ¶ 15. Two hours later, she got into her car while asleep and drove, wrecking the vehicle and causing herself serious injuries. *Id*. at ¶¶ 15 – 17.

II. Ambien CR

As acknowledged in Plaintiff's Amended Complaint, Ambien CR (zolpidem) is an FDA-approved prescription medication indicated for the treatment of insomnia. *See* "Exhibit A," Approval Letter dated September 2, 2005; "Exhibit B," Ambien CR label dated December 2007.[1] The label for Ambien CR that was in effect in December 2008—the date Plaintiff alleges she was prescribed the Ambien CR she took just before her sleep driving episode—contains the following relevant warning:

> **Abnormal thinking and behavioral changes**
>
> Complex behaviors such as "sleep-driving" (i.e., driving while not fully awake after ingestion of a sedative-hypnotic, with amnesia for the event) have been reported with sedative-hypnotics, including zolpidem. These events can occur in sedative-hypnotic-naïve as well as in sedative-hypnotic-experienced persons. Although behaviors such as "sleep-driving" may occur with Ambien CR along at

[1] This Court may consider these documents, which are "incorporated" in Plaintiff's Amended Complaint by reference and matter subject to judicial notice, without converting sanofi-aventis' motion to dismiss to a motion for summary judgment. *See Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir. 2000). The Ambien CR Approval Letter and Label are central to Plaintiff's claims that are premised on the theory that sanofi-aventis failed to warn of Ambien CR's potential to cause Plaintiff's alleged sleep driving. *See, generally*, Amended Compl. The labels are also matters of public record not subject to reasonable dispute of which this Court may take judicial notice. Fed. R. Evid. 201(b); *Norris v. Hearst Trust*, 500 F.3d 454, 461 n.9 (5th Cir. 2007); *see U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 2010 WL 3909447, at 755 & 756 n.9 (S.D. Tex. Sept. 30, 2010) (taking judicial notice of FDA notification letters and other documents cited by parties from FDA website as matters of public record); *see also Ebel v. Eli Lilly and Co.*, 536 F. Supp. 2d 767, 781 (S.D. Tex. 2008) (taking judicial notice that Paxil is a "centrally acting drug" based on prescribing information on FDA website).

> therapeutic doses, the use of alcohol and other CNS depressants with Ambien CR appears to increase the risk of such behaviors, as does the use of Ambien CR at doses exceeding the maximum recommended dose. Due to the risk to the patient and the community, discontinuation of Ambien CR should be strongly considered for patients who report a "sleep-driving" episode. Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with "sleep-driving", patients usually do not remember these events. Amnesia, anxiety and other neuro-psychiatric symptoms may occur unpredictably.

Ex. B at p. 3 (s*ee also* Medication Guide, beginning on p. 22 of Ex B, which also references "sleep-driving").

ARGUMENT

I. Standards

Federal Rule of Civil Procedure 12(b)(6) authorizes dismissal of a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a Rule 12(b)(6) motion, the plaintiff must plead 'enough facts to state a claim to relief that is plausible on its face.'" *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A pleading that offers "labels and conclusions," "naked assertion[s]" devoid of "further factual enhancement," or "a formulaic recitation of the elements of a cause of action will not do." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 555, 557).

Federal Rule of Civil Procedure Rule 8(a)(2) requires that a plaintiff plead facts showing that he or she is entitled to relief "in order to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555 (internal quotation marks and modifications omitted). Federal Rule of Civil Procedure Rule 9(b) states that "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The Fifth Circuit "interprets Rule 9(b) strictly, requiring the plaintiff to

'specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent.'" *Flaherty & Crumrine Preferred Income Fund, Inc. v. TXU Corp.*, 565 F.3d 200, 207 (5th Cir. 2009) (quoting *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 177, 179 (5th Cir. 1997) (holding Rule 9(b) requires that a plaintiff set forth the "who, what, when, where, and how" of the alleged fraud)).

None of Plaintiff's claims satisfies these standards.

II. Plaintiff Fails to State a Claim under the Learned Intermediary Doctrine

As the Amended Complaint acknowledges, Ambien CR is a prescription drug that Plaintiff obtained through her doctor. *See* Amended Compl. at ¶¶ 11-13. Accordingly, the learned intermediary doctrine applies to all of Plaintiff's claims and any duty to warn ran to Plaintiff's doctors. *See Ebel v. Eli Lilly and Co.*, 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008), *aff'd*, 321 Fed. Appx. 350 (5th Cir. Mar. 30, 2009) (applying doctrine to "strict liability, negligence, misrepresentation, and breach of warranty claims."); *Wyeth-Ayerst Labs. v. Medrano*, 28 S.W.3d 87, 93-94 (Tex. App.—Texarkana 2000) (applying doctrine to DTPA claims).

Nowhere in the Complaint does Plaintiff allege that the warning to Plaintiff's prescribing physician was inadequate. *See, generally,* Amended Complaint. Indeed, under Texas law, sanofi-aventis' warning was adequate as a matter of law because, as discussed above, sanofi-aventis warned of sleep driving. *See Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied) ("[I]f a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law"); *see also Brumley v. Pfizer, Inc.*, 149 F.Supp.2d 305, 310 (S.D. Tex. 2001) (citing *Rolen*).

A. Plaintiff's Amended Complaint Fails to State a Claim for Negligence.

The Amended Complaint's allegations fail to establish both the breach and causation elements of its negligence claim, and therefore must be dismissed. *See* Amended Compl. ¶¶ 29 – 42. In Texas, the elements required to establish a negligence claim are: (1) a legal duty to use due care; (2) a breach of that duty; (3) proximate causation of the resulting injury; and (4) damages. *Kroger v. Elwood*, 197 S.W.3d 793, 794 (Tex. 2006) (per curiam). Plaintiff's negligence claim is premised on sanofi-aventis' failure to warn of the sleep driving associated with the ingestion of Ambien CR. *See, e.g.,* Amended Compl. ¶¶ 36, 38. Accordingly, the learned intermediary doctrine applies. *See supra* § II.

First, Plaintiff has failed to allege facts showing that sanofi-aventis either owed a cognizable duty to Plaintiff's prescribing physician or that it breached this duty. The Ambien CR label in effect at the time of the alleged incident carried a warning regarding sleep driving. *See* Ex. B. The Amended Complaint does not even address this warning. *See Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x. 597, 609 (11th Cir. July 29, 2008) (affirming dismissal of failure-to-warn claim where the complaint failed to "recite the contents of the warning label or the information available to [decedent's] physician or otherwise describe the manner in which the warning was inadequate"). Plaintiff's negligence claim should therefore be dismissed.

Second, the Amended Complaint fails to allege what warnings or materials *Plaintiff's* prescribing doctor ever received or reviewed or that such warnings were inadequate, much less that he or she would not have prescribed Ambien CR if the warning were different. *See* Amended Compl. ¶¶ 29 - 42. Accordingly, the Amended Complaint fails to allege any facts showing causation on its failure to warn claims. *See Pustejovsky v. Pliva*, 623 F.3d 271, 276 (5th Cir. 2010) ("…[t]he learned-intermediary doctrine … requires that the inadequate warning was a

'producing cause' of the plaintiff's injuries. Therefore, a plaintiff who complains that a prescription drug warning is inadequate must also show that the alleged inadequacy caused her doctor to prescribe the drug for her.") (citation and internal quotation marks omitted); *Ebel v. Eli Lilly and Co.*, 536 F. Supp. 2d 767, 777 (S.D. Tex. 2008) (holding plaintiff claiming failure to warn through improper marketing practices must show that the marketing "reached and [a]ffected the prescribing physician"), *aff'd*, 321 f. App'x. 350, 355-58 (5th Cir. Mar. 30, 2009).

B. Plaintiff's Amended Complaint Fails to State a Strict Liability Claim.

Texas has adopted Section 402A of the Restatement (Second) of Torts, under which a plaintiff claiming strict liability must allege (1) a product defect; (2) that existed at the time the product left the manufacturer's hands; (3) made the product unreasonably dangerous; and (4) was a producing cause of the plaintiff's injuries. *Parsons v. Ford Motor Co.*, 85 S.W.3d 323, 329 (Tex. App. – Austin 2002). A prescription drug product that is "'properly prepared[ ] and accompanied by proper directions and warnings[ ] is not defective, nor is it unreasonably dangerous.'" *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (quoting Restatement (Second) Torts § 402A cmt. K (1965)).

In support of her strict liability claim, Plaintiff relies on the same deficient failure-to-warn theory as her negligence claim, simply alleging that Ambien CR "was defective unreasonably dangerous, unfit for its intended use." Amended Compl. ¶ 45. These bare legal conclusions provide insufficient notice of Plaintiff's actual claims. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). Moreover, as discussed above, this claim fails under the learned intermediary doctrine because Plaintiff has failed to allege what warnings or marketing materials her prescribing doctors received, how those warnings or materials were deficient, or how those warnings or materials influenced the doctor's decision to prescribe Ambien CR.

C. Plaintiff's Amended Complaint Fails to State a Claim for Fraud.

Plaintiff's fraud claims suffer from the same collective and conclusory pleading deficiencies as her negligence and strict liability claims, and thus fail under the demanding standards of Federal Rule 9(b). *See* Amended Compl. ¶¶ 55 - 66. As discussed above, the learned intermediary doctrine applies. *See supra*, § II.

A fraud claim under Texas law is actionable when: (1) a material misrepresentation was made; (2) the representation was false; (3) the falsity of the representation was known to be false when made or was asserted without knowledge of its truth; (4) the representation was intended to be acted upon; (5) the representation was relied upon; and (6) injury occurred as a result. *Arete Partners, L.P. v. Gunnerman*, 594 F.3d 390, 394 (5th Cir. 2010). "Courts in Texas have consistently held that fraud by nondisclosure or concealment requires proof of all of the elements of fraud by affirmative misrepresentations, including fraudulent intent, with the exception that the misrepresentation element can be proven by the nondisclosure or concealment of a material fact in light of a duty to disclose." *United Teacher Assocs. Ins. Co. v. Union Labor Life Ins. Co.*, 414 F.3d 558, 567-68 (5th Cir. 2005).

Under Rule 9(b), fraud allegations must be made with particularity as to "time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby." *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 177 (5th Cir. 1997); *see also Hernandez v. Ciba-Geigy Corp. USA*, 200 F.R.D. 285, 291 (S.D. Tex. 2001) (dismissing fraud claim where plaintiff failed to "cite one statement that was made" in any of the promotion material for Ritalin that was allegedly misleading). Furthermore, "articulating the elements of fraud with particularity requires a plaintiff to . . . explain why the statements [that were allegedly made] were fraudulent." *Id.* These requirements

must be adhered to "strictly." *Flaherty & Crumrine Preferred Income Fund, Inc. v. TXU Corp.*, 565 F.3d 200, 207 (5th Cir. 2009).

But Plaintiff's Amended Complaint merely presents an amalgamation of nonspecific and conclusory statements about sanofi-aventis' allegedly fraudulent conduct. *See* Amended Compl. ¶¶ 57, 59, 62, 63. And there is no specificity to the content of each allegedly fraudulent statement, when each such statement was made and received, what was false and material about the statement, and whether the statement was relied upon to her detriment by Plaintiff or her prescribing doctors. *See id* at ¶¶ 55 - 66. These nonspecific and conclusory allegations fail to set forth the "who, what, when, where, and how" of the alleged fraud on Plaintiff or her prescribing doctors that the Amended Complaint claims caused her injury, as required by Federal Rule 9(b). *Williams*, 112 F.3d at 179.

Nor has Plaintiff alleged facts showing how any such fraudulent statements proximately caused Plaintiff's ingestion of Ambien CR, and thus her alleged sleep driving incident. *See Pustejovsky*, 623 F.3d at 276, 277; *In re Norplant Contraceptive Prods. Litig*., 165 F.3d 374, 279 (5th Cir. 1999); *See Ebel v. Eli Lilly and Co*., 536 F. Supp. 2d 767, 777 (S.D. Tex. 2008), *aff'd*, 321 Fed. Appx. 350 (5th Cir. Mar. 30, 2009). Plaintiff thus fails to allege the required elements of a fraud claim under Texas law.

D. Plaintiff's Amended Complaint Fails to State a Claim for Breach of Warranties.

Plaintiff's breach of warranty claims rely on the same deficient failure to warn allegations that support her negligence, strict liability and fraud claims. *See* Amended Compl. at ¶¶ 49 – 54, 74 – 79. Like her other claims, Plaintiff's warranty claims are subject to the learned intermediary doctrine. *See supra*, § II. But nowhere in her Amended Complaint does Plaintiff state what warranties were made to Plaintiff's prescribing physician nor how the alleged

warranties were breached. *See* Amended Compl. at ¶¶ 49–54, 74–79. Without those facts, Plaintiff's allegations amount to what the Supreme Court described as "an unadorned, the-defendant-unlawfully-harmed-me-accusation," and do not state plausible claims for relief. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009).

E. Plaintiff's Amended Complaint Fails to State a Claim for Unfair Trade Practices.

Plaintiff's "unfair trade practices" allegations are so woefully deficient that sanofi-aventis cannot begin to make out even the intended cause of action. Sanofi-aventis is merely told that "[d]efendant willful and knowing commission of multiple unlawful unfair and deceptive acts in designing, manufacturing, marketing, distributing and/or selling Ambien CR has caused injury to Plaintiff." *See id.* at ¶73. Plaintiff fails to plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *See Iqbal*, 129 S.Ct. at 1949; *see also Steen v. Medtronic, Inc.*, 2010 WL 2573455, at *1 (N.D. Tex. Jun. 25, 2010) (recognizing that the plausibility standard requires more than a sheer possibility that a defendant has acted unlawfully) (citations omitted).

Morever, assuming that Plaintiff's "unfair trade practices" claim is based on the same failure to warn theory she relies on for her other claims, Plaintiff's claim fails for the same reasons discussed previously.

III. Plaintiff's Amended Complaint Must be Dismissed Because Plaintiff's Claims are Foreclosed Under CRPC 82.007

Sanofi-aventis is also immune from liability for Plaintiff's claims because its warnings were FDA-approved. Under Civil Practice & Remedies Code § 82.007, Texas created a rebuttable presumption that pharmaceutical manufacturers "are not liable" for an alleged failure to warn if the FDA has approved the warnings:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings for information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> (1) the warnings or information that has accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301, *et seq*.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended.

Tex. Civ. Prac. & Rem. Code § 82.007(a) (emphasis added).

The Ambien CR label was approved by the FDA. *See* Ex. A; 21 U.S.C. § 355(b)(1)(F); 21 U.S.C. § 355(d). Consequently, sanofi-aventis is entitled to the presumption that its warnings for Ambien CR were adequate and that it is "not liable" as a matter of law. *See Ebel*, 536 F. Supp. 2d at 773-74 (applying Section 82.007 to FDA-approved label).

Additionally, Plaintiff has alleged no facts that would rebut the presumption that sanofi-aventis' FDA-approved label shields it from liability. *See* Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b); *In re Aredia and Zometa*, 2008 WL 2944910, at *3 (M.D. Tenn. Jul. 25, 2008). Thus, sanofi-aventis is entitled to a presumption of no liability. Because she states no cognizable legal theory against sanofi-aventis, Plaintiff's claims should be dismissed. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009) (holding that dismissal is proper in the absence of sufficient facts to support a cognizable theory).

IV. Plaintiff's Amended Complaint Should be Dismissed With Prejudice.

Plaintiff's claims should be dismissed with prejudice because there is no valid excuse for her failure to plead proper claims at this late date. Plaintiff and her counsel have had notice of Plaintiff's pleading deficiencies through sanofi-aventis' Motion to Dismiss Plaintiff's Original Petition and have had an extensive opportunity to develop and properly plead her current claims.

Respectfully submitted,

By: */s/ Kathleen A. Frazier*

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CERTIFICATE OF SERVICE

I hereby certify that on the 25th day of May, 2011, I served DEFENDANT SANOFI AVENTIS U.S. LLC'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT in accordance with the Federal Rules of Civil Procedure as indicated below:

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